

**Neovanta Medical AB
Goteborg, Sweden**

March 15, 2002

Kathy Daws-Kopp
Center for Devices and Radiological Health
Office of Device Evaluation (HFZ-470)
9200 Corporate Boulevard
Rockville, MD 20850

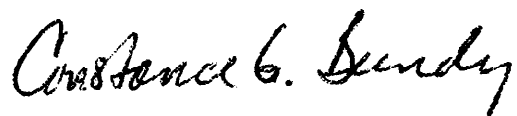
Re: Information for OBGYN Panel Review
Neovanta Medical AB STAN® S21 Fetal Heart Monitor
PMA P020001

Enclosed please find information for members of the OBGYN Panel selected to review the Neovanta Medical PMA on April 22, 2002.

All information contained in the panel package is releasable to the public and may be discussed with all interested parties.

If more information is needed or there are questions regarding the package, contact Constance Bundy, Authorized Representative for Neovanta Medical AB.

Regards,

A handwritten signature in black ink that reads "Constance G. Bundy". The script is cursive and fluid, with the first name "Constance" being larger and more prominent than the last name "Bundy".

Constance G. Bundy, Consultant to Neovanta Medical AB
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Panel Package - Table of Contents

Volume I

Cover Letter

Introduction - "Intrapartum Fetal Monitoring and the Fetal ECG -Time for a Change"

1. Background Material
 - a. Educational material
Textbook
Interactive CD
 - b. Literature References
Intrapartum Fetal Monitoring: Cardiotocography vs. Cardiotocography plus ST Analysis of the Fetal ECG. A Swedish Randomized Control Trial
Improved Neonatal outcome with ST analysis of Fetal Electrocardiogram
 - c. Bibliography listing
2. Summary of Safety and Effectiveness
3. Device Description

Volume II

4. Clinical Information
 - a. Swedish Randomized Controlled Trial (RCT)
Study description and results (PMA Section VII)
Original RCT protocol: Randomized Controlled Trial of CTG vs. CTG+ST
Retraining Phase after Interim Analysis at Sahlgrenska University Hospital
Case report forms
 - b. EU Sponsored Program for the Establishment of Centers of Excellence
Proposal
Summary of the STAN S21 Clinical Database—data from the City of Gothenburg
5. Prior Clinical Information
 - a. Chart of prior clinical studies
 - b. Development of ST analysis method/device
"Intrapartum Fetal Monitoring and the Fetal ECG - Time for a Change"
(Refer to Introduction)

Neovanta Medical AB - STAN® S21 Fetal Heart Monitor
PMA P020001
March 15, 2002

5. Prior Clinical Information (continued)

c. Confirmation/validation of methods

Plymouth Randomized Trial of Cardiotocogram only vs. ST Waveform plus

Cardiotocogram for Intrapartum Monitoring in 2400 Cases

European Community Multicenter Trial

ST Analysis of the Fetal ECG during labor--Nordic Observational

Multicenter Study

Westgate thesis (available upon request)